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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,547

08/27/2003

Carsten-Peter Carstens

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EXAMINER

MITCHELL, LAURA MCGILLEM

ART UNIT

PAPER NUMBER

1636

NOTIFICATION DATE

DELIVERY MODE

02/26/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/649,547	<b>Applicant(s)</b> CARSTENS, CARSTEN-PETER	
	<b>Examiner</b> LAURA M. MITCHELL	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 12-19 is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/2007 has been entered.

It is noted that claim 1 has been amended in the response filed 11/15/2007. Claims 1-19 are under examination. It is noted that in the previous Office Action (mailed 3/27/2007), claim 11 was indicated as allowable. However after further consideration, new grounds of rejection have been applied below.

### ***Claim Rejections - 35 USC § 112***

Applicant's amendment of claim 1 and arguments, see REMARKS, filed 11/15/2007, with respect to claim 1-3 have been fully considered and are persuasive. The rejection of claim 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Griffiths et al (US Patent No. 6,492, 160, filed 6/25/1998). This is a NEW rejection.**

Claim 11 is drawn to a vector comprising a double stranded origin of replication (ori) of a rolling circle replicon. It is noted that the claim does not recite any structural characteristics that would further limit the double stranded ori as being "of a rolling circle replicon". Therefore, this limitation will be given the broadest reasonable interpretation such that, absence evidence to the contrary, a double stranded ori would be "of a rolling circle replicon". It is also noted that the claim is drawn to a vector, and therefore a prior art reference teaching the structural limitations of the vector as claimed do not have to teach that the vector is a "product" of any particular process or making that vector in order to anticipate the vector. It is also noted that as the claim is written, it does not exclude other elements from the vector.

Griffiths et al teach a vector comprising gene sequences encoding light and heavy chains of antibodies (see Figure 3A, in particular), which meets the limitation of a gene of interest. Griffiths et al teach that the vector also comprises sequences encoding marker proteins (see Figure 3A and column 20, lines 48-67, in particular), which meets the limitation of a selectable marker gene. The vector shown in Figure 3 also comprises a "lox" site (see column 12, lines 64-67, for example) which meets the limitation of a LoxP site specific recombination recognition site. Griffiths et al teach that other site

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specific recombination recognition sites can be LoxP1, LoxP2, LoxP3 and LoxP4 (see column 13, lines 30-42, for example). Griffiths et al teach that the vector comprises origins of replication identified as "ori1" and "M13 ori" (see Figure 3A, in particular). Griffiths et al disclose a kit comprising two vectors to be combined to make one vector. Griffiths et al teach that one of these vectors comprises an ori for a single stranded bacteriophage (see column 15, line 6-12, in particular). Griffiths et al teach that the bacteriophage can be an f1 bacteriophage (see column 24, lines 60-67, for example). The instant specification discloses double stranded ori of f1 bacteriophage (see claim 7, for example). Griffiths et al teach an embodiment in which a phagemid vector comprises an ori for a bacteriophage, as well as an ori of a plasmid (see column 10, lines 6-10, for example). Griffiths et al teach that the vector comprising an origin of double stranded replication that is compatible with another ori that originated from a phagemid (e.g. p15a, RSF1010 and ColE1 ori will co-exist in the same cell (see column 20, lines 48-67, in particular), which meets the limitation of a vector comprising a double stranded ori, which absent contrary evidence would be "of a rolling circle replicon", and comprising a single stranded ori.

Griffiths et al exemplify a vector in which the variable and constant antibody light chains are adjacent to a lox site on one side and on the other side is adjacent to a selectable marker<sup>1</sup>, an M13 ori and then an ori1. Although Griffiths et al do not specifically teach a vector in which the gene of interest is interposed (see instant paragraphs 0028-0029) between said double-stranded ori of a rolling circle replicon and said site-specific recombination recognition site as required by claim 11, all of the

structural elements are present. As the claim is written, it does not require that the vector be a product or any particular process making that vector, or that the vector is used for any particular function. Therefore it would constitute only routine optimization to modify the elements of the vector as claimed so that the sequences encoding the antibody light chains are interposed between double-stranded ori and the loxP recombination recognition site. Therefore, Griffiths et al anticipate the product vector of claim 11.

### ***Conclusion***

Claims 1-10 and 12-19 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA M. MITCHELL whose telephone number is (571)272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem Mitchell  
Examiner  
2/14/2008

/Celine X Qian Ph.D./  
Primary Examiner, Art Unit 1636